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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/092,243	03/06/2002	Jeffrey Daniel Hillman	00-505-I	9604
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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER

SHIBUYA, MARK LANCE

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,243

Applicant(s)

HILLMAN, JEFFREY DANIEL

Examiner

Mark L. Shibuya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-12, drawn to methods of identifying a polynucleotide of a microbe, classified in class 435, subclass 6.
- II. Claims 13-18, drawn to methods of comparing polynucleotides of a microbe that are expressed *in vivo* at different stages and routes of infection, classified in class 435, subclass 6.
- III. Claims 19-22, drawn to methods of confirming an animal model of microbial infection, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I-IV are unrelated, each from the other.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions functions because the methods of identifying polynucleotides of a microbe that are expressed *in vivo*, (as in Group I), is a different function and effect from methods of comparing polynucleotides of microbes from diseases that differ by stage or route of infection, as in Group II. The methods of both Groups I and II have different functions and effects from the method of confirming an animal model of microbial infection, as in Group III.

Because these inventions are distinct for the reasons given above and it is necessary to search for each one of the distinct subjects in places where no pertinent art to each of the other subject exists, restriction for examination purposes as indicated is proper. MPEP 808.02.

Election of Species

Election of Species, Distinct Species Claimed

2. This application contains claims directed to the following patentably distinct species of the claimed invention: an animal that is a human, baboon, chimpanzee, macaque, cattle, sheep, pig, horse, goat, dog, cat, rabbit, guinea pig, rat, mouse, chicken, duck, fish, or shellfish.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6, 11, and 19 are generic (if Group I or Group III is elected).

3. This application contains claims directed to the following patentably distinct species of the claimed invention: a microbe that is a bacterium, a virus, a parasite, a prion, or a fungus.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 9 is generic (if Group I is elected).

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4. Applicant is advised that a reply to this requirement must include an **identification of the species that is elected** consonant with this requirement, and a **listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of Species, Distinct Species Disclosed Burdensome Search

5. If Group I is elected, Claim 3 is generic to a plurality of disclosed patentably distinct species comprising nitrocellulose, nylon, polystyrene, polyvinylchloride, latex, fiberglass, glass, microsphere, liposome, sepharose, sephadex or a magnetic particle. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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6. If Group I is elected, Claim 10 is generic to a plurality of disclosed patentably distinct species comprising microbes that are *Candida*, *Aspergillus*, *Sporothrix* and so on. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The

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fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Shibuya
Examiner
Art Unit 1639

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PADMASHRI PONNALURI
PRIMARY EXAMINER